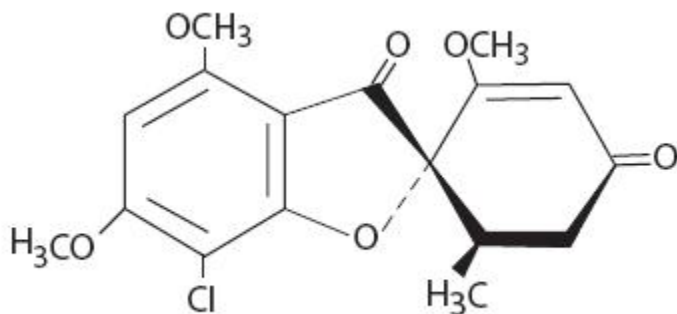


GRISEOFULVIN - griseofulvin suspension
TEVA Pharmaceuticals USA Inc

DESCRIPTION

Griseofulvin is an antibiotic derived from a species of *Penicillium*. Chemically, griseofulvin is designated as 7-Chloro-2',4,6-trimethoxy-6'β-methylspiro[benzofuran-2(3H),1'-[2]cyclohexene]-3,4'-dione and has the following structural formula:



C₁₇H₁₇ClO₆ M.W. 352.77

Griseofulvin is a pink to orange colored, tutti-frutti flavored, uniform suspension.

Each 5 mL of griseofulvin suspension contains 125 mg of griseofulvin microsize and also contains the following inactive ingredients: artificial flavors, carboxymethyl cellulose sodium, dl-alpha-tocopherol, FD&C red #40, FD&C yellow #6, glycerin, hydrochloric acid, methylparaben, microcrystalline cellulose, propylene glycol, propylparaben, simethicone emulsion, sodium alginate, sodium hydroxide, sodium lauryl sulfate and sucrose.

CLINICAL PHARMACOLOGY

Griseofulvin acts systemically to inhibit the growth of *Trichophyton*, *Microsporum*, and *Epidermophyton* genera of fungi. Fungistatic amounts are deposited in the keratin, which is gradually exfoliated and replaced by noninfected tissue.

Griseofulvin absorption from the gastrointestinal tract varies considerably among individuals, mainly because of insolubility of the drug in aqueous media of the upper G.I. tract. The peak serum level found in fasting adults given 0.5 gm occurs at about four hours and ranges between 0.5 and 2 mcg/mL.

It should be noted that some individuals are consistently "poor absorbers" and tend to attain lower blood levels at all times. This may explain unsatisfactory therapeutic results in some patients. Better blood levels can probably be attained in most patients if griseofulvin is administered after a meal with a high fat content.

INDICATIONS AND USAGE

Major indications for griseofulvin are:

- Tinea capitis (ringworm of the scalp)
- Tinea corporis (ringworm of the body)
- Tinea pedis (athlete's foot)
- Tinea unguium (onychomycosis; ringworm of the nails)
- Tinea cruris (ringworm of the thigh)
- Tinea barbae (barber's itch)

Griseofulvin inhibits the growth of those genera of fungi that commonly cause ringworm infections of the hair, skin, and nails, such as:

- Trichophyton rubrum*
- Trichophyton tonsurans*
- Trichophyton mentagrophytes*
- Trichophyton interdigitalis*
- Trichophyton verrucosum*
- Trichophyton sulphureum*
- Trichophyton schoenleinii*
- Microsporum audouinii*
- Microsporum canis*
- Microsporum gypseum*
- Epidermophyton floccosum*
- Trichophyton megnini*
- Trichophyton gallinae*
- Trichophyton crateriform*

Note: Prior to therapy, the type of fungi responsible for the infection should be identified. The use of the drug is not justified in minor or trivial infections which will respond to topical antifungal agents alone.

It is *not* effective in:

Bacterial infections

Candidiasis (Moniliasis)

Histoplasmosis

Actinomycosis

Sporotrichosis

Chromoblastomycosis

Coccidioidomycosis

North American Blastomycosis

Cryptococcosis (Torulosis)

Tinea versicolor

Nocardiosis

CONTRAINDICATIONS

This drug is contraindicated in patients with porphyria, hepatocellular failure, and in individuals with a history of hypersensitivity to griseofulvin.

Two cases of conjoined twins have been reported in patients taking griseofulvin during the first trimester of pregnancy. Griseofulvin should not be prescribed to pregnant patients.

WARNINGS

Prophylactic Usage

Safety and efficacy of prophylactic use of this drug has not been established.

Chronic feeding of griseofulvin, at levels ranging from 0.5 to 2.5% of the diet, resulted in the development of liver tumors in several strains of mice, particularly in males. Smaller particle sizes result in an enhanced effect. Lower oral dosage levels have not been tested. Subcutaneous administration of relatively small doses of griseofulvin once a week during the first three weeks of life has also been reported to induce hepatomata in mice. Although studies in other animal species have not yielded evidence of tumorigenicity, these studies were not of adequate design to form a basis for conclusions in this regard.

In subacute toxicity studies, orally administered griseofulvin produced hepatocellular necrosis in mice, but this has not been seen in other species. Disturbances in porphyrin metabolism have been reported in griseofulvin-treated laboratory animals. Griseofulvin has been reported to have a colchicine-like effect on mitosis and cocarcinogenicity with methylcholanthrene in cutaneous tumor induction in laboratory animals.

Reports of animal studies in the Soviet literature state that a griseofulvin preparation was found to be embryotoxic and teratogenic on oral administration to pregnant Wistar rats. Rat reproduction studies done in the United States and Great Britain were inconclusive in this regard, and additional animal reproduction studies are underway. Pups with abnormalities have been reported in the litters of a few bitches treated with griseofulvin.

Suppression of spermatogenesis has been reported to occur in rats but investigation in man failed to confirm this.

PRECAUTIONS

Patients on prolonged therapy with any potent medication should be under close observation. Periodic monitoring of organ system function, including renal, hepatic and hemopoietic, should be done.

Since griseofulvin is derived from species of penicillin, the possibility of cross sensitivity with penicillin exists; however, known penicillin-sensitive patients have been treated without difficulty.

Since a photosensitivity reaction is occasionally associated with griseofulvin therapy, patients should be warned to avoid exposure to intense natural or artificial sunlight. Should a photosensitivity reaction occur, lupus erythematosus may be aggravated.

Drug Interactions

Patients on warfarin-type anticoagulant therapy may require dosage adjustment of the anticoagulant during and after griseofulvin therapy. Concomitant use of barbiturates usually depresses griseofulvin activity and may necessitate raising the dosage.

The concomitant administration of griseofulvin has been reported to reduce the efficacy of oral contraceptives and to increase the incidence of breakthrough bleeding.

ADVERSE REACTIONS

When adverse reactions occur, they are most commonly of the hypersensitivity type such as skin rashes, urticaria and rarely, angioneurotic edema and may necessitate withdrawal of therapy and appropriate countermeasures. Paresthesias of the hands and feet have been reported rarely after extended therapy. Other side effects reported occasionally are oral thrush, nausea, vomiting, epigastric distress, diarrhea, headache, fatigue, dizziness, insomnia, mental confusion and impairment of performance of routine activities.

Proteinuria and leukopenia have been reported rarely. Administration of the drug should be discontinued if granulocytopenia occurs.

When rare, serious reactions occur with griseofulvin, they are usually associated with high dosages, long periods of therapy, or both.

DOSAGE AND ADMINISTRATION

Accurate diagnosis of the infecting organism is essential. Identification should be made either by direct microscopic examination of a mounting of infected tissue in a solution of potassium hydroxide or by culture on an appropriate medium.

Medication must be continued until the infecting organism is completely eradicated as indicated by appropriate clinical or laboratory examination. Representative treatment periods are tinea capitis, 4 to 6 weeks; tinea corporis, 2 to 4 weeks; tinea pedis, 4 to 8 weeks; tinea unguium – depending on rate of growth – fingernails, at least 4 months; toenails, at least 6 months.

General measures in regard to hygiene should be observed to control sources of infection or reinfection. Concomitant use of appropriate topical agents is usually required, particularly in treatment of tinea pedis since in some forms of athlete's foot, yeasts and bacteria may be involved. Griseofulvin will not eradicate the bacterial or monilial infection.

Adults

A daily dose of 500 mg will give a satisfactory response in most patients with tinea corporis, tinea cruris, and tinea capitis.

For those fungus infections more difficult to eradicate such as tinea pedis and tinea unguium, a daily dose of 1 gram is recommended.

Children

Approximately 5 mg per pound of body weight per day is an effective dose for most children. On this basis the following dosage schedule for children is suggested:

Children weighing 30 to 50 pounds – 125 mg to 250 mg daily

Children weighing over 50 pounds – 250 mg to 500 mg daily

HOW SUPPLIED

Griseofulvin Oral Suspension USP is available as a pink to orange colored, tutti-frutti flavored, uniform suspension containing 125 mg/5 mL griseofulvin microsize in a 4 ounce (120 mL) bottle.

PHARMACIST: Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure as required.

This product is protected by a tamper-resistant seal around the neck opening. If the seal has been broken or is removed, do not use the product. Return the product to place of purchase.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

SHAKE WELL BEFORE USING

Manufactured In India By:

Cipla Ltd.

Goa, India

Manufactured For: 0093

TEVA PHARMACEUTICALS USA 09/07

Sellersville, PA 18960 B2

GRISEOFULVIN

ORAL SUSPENSION USP

(microsize)

PRINCIPAL DISPLAY PANEL

NDC 0093-7102-12
GRISEOFULVIN
Oral Suspension USP
(microsize)
125 mg/5 mL

Each 5 mL (one teaspoonful) contains:
125 mg griseofulvin USP (microsize) in a pink to orange colored, uniform suspension.

This product is protected by a tamper-resistant seal around the neck opening. If the seal has been broken or is removed do not use the product. Return the product to place of purchase.

Rx only

4 fl oz (120 mL)

TEVA

Usual Adult Dosage: Four teaspoonfuls (500 mg) daily.

Usual Children's Dosage: One (125 mg) to four (500 mg) teaspoonfuls daily depending on age and weight. See package insert for full prescribing information.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

SHAKE WELL BEFORE USING

Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Rev. A 8/2007

Manufactured In India By:
Cipla Ltd.; Goa, India


Manufactured For:
TEVA PHARMACEUTICALS USA
Sellersville, PA 18960


979VB Code No.:
GO/DRUGS/536


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Principal Display Panel Text

NDC 0093-7102-12

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